SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

FEB 1 2 2003

The assigned 510(k) number is: K024164

Applicant information:

Date Prepared:	February 4, 2003
Name:	Metro Optics, Inc.
Address	15802 Vision Drive Pflugerville, TX 78660
Contact Person:	Mr. Steve Webb Vice President
Phone Number:	(512) 251-2382
Fax:	(512) 251-6554
Official Correspondent: Regulatory Consultant:	Med-Vice Consulting, Inc. Ms. Deanna Werber 623 Glacier Drive Grand Junction, CO 81503
Phone Number:	(970) 243-5490
Fax Number:	(970) 243 -5501

Device Information:

Regulatory Classification:	Class II
Product Code:	HQD
Trade Name:	Comfort*Kone*™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank)
Purpose for 510(k)	Addition of three RGP materials to a previously cleared design and indication for use. (K990264)
Classification Name:	Lenses, Contact (other material), Daily Wear

Equivalent Devices:

The Comfort*Kone*™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens is substantially equivalent to the predicate device identified below in terms of intended use and design.

Predicate device manufacturer:
1.) Metro Optics of Austin, Inc.
15802 Vision Drive
Pflugerville, TX 78660
510(k) 990264

Device name:
Comfort*Kone*™, Keratoconus, Daily Wear
510(k) #: K990264

Device Description:

The Comfort*Kone*™ Keratoconus Aspheric Contact Lens is fabricated from the hydrophobic contact lens materials (hybufocon A, filofocon A, pemufocon A). When placed on the human cornea, the Comfort*Kone*™ Keratoconus Aspheric rigid gas permeable contact lenses act as a refracting medium to focus light rays upon the retina.

The Comfort*Kone*™ is a aspheric contact lens. It is designed to provide optimum comfort and visual acuity to the keratoconus patient. The Comfort*Kone*™ lens design begins with a spherical 4.0 mm optic zone that fits the peak of the cone and provides for good visual acuity. The lens then flattens into the aspheric curve, which is considered the fitting curve of the lens. The aspheric curve will vary in rate of change depending on how far the keratoconus has advanced and creates optimal corneal alignment. The design finishes with two junctionless peripheral aspheric curves to maintain alignment.

Metro Optics of Austin, Inc., has been granted referencing rights from the button manufacturers. The physical properties of the lenses can be referenced in the corresponding 510(k)'s.

Contamac	HyBrid FS (hybufocon A) reference	510(k) K021977
Innovision	Hydro2 (filofocon A) reference	510(k) K000485
Innovision	Accucon (pemufocon A) reference	510(k) K944223

Intended Use:

The Comfort*Kone*™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank) is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be disinfected with a chemical disinfection system.

Substantial Equivalence:

The new device will be manufactured according to specified process controls and a Quality Management System certified to QSR guidelines. The new device will undergo manufacturing, packaging and other process procedures similar to RGP devices currently marketed and distributed by Metro Optics, Inc. in the USA. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the Metro Optics, Inc. Comfort*Kone*™, Keratoconus, Daily Wear 510(k) #K990264. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and *does not raise* different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates that the production method, lens function and material of the Comfort*Kone*™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens are substantially equivalent to the predicate device. In addition, the indication, intended use, production method, water content, polymer, Dk value, specific gravity, are as well substantially equivalent to the predicate device.

SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial Equivalence Matrix

	Characteristic	New Device ComfortKone Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A)	Predicate Device ComfortKone Keratoconus Aspheric (paflufocon C)
1.)	**INDICATION**	Daily wear, Rigid Gas Permeable (RGP) contact lens	Daily wear, Rigid Gas Permeable (RGP) contact lens
2.)	**INTENDED USE**	Daily wear for persons requiring Keratoconus management. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not aphakic persons with non-diseaased eyes.	Daily wear for persons requiring Keratoconus management. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia, and astigmatism) in aphakic and not aphakic persons with non-diseaased eyes.
3.)	**PRODUCTION METHOD**	Lathe-Cut	Lathe-Cut
4.)	**RGP MATERIAL common name**	HyBrid FS Hydro2 Accucon	Fluroperm 30
a.	Water Content	(hybufocon A) <1% (filofocon A) < 1% (pemufocon A) < 1%	< 1%
b.	Polymer/USAN	HyBrid FS (hybufocon A) Hydro2 (filofocon A) Accucon (pemufocon A)	Fluroperm 30 (paflufocon C)
c.	Specific Gravity	(hybufocon A) 1.18 (filofocon A) 1.14 (pemufocon A) 1.16	(paflufocon C) 1.14
d.	Oxygen Permeability	(hybufocon A) = 23 (filofocon A) = 50 (pemufocon A) = 25	30
e.	Wetting Angle	(hybufocon A) = immeasurable * (filofocon A) = <5 ** (pemufocon A) = <25 **	12.8
f.	Light Transmittance	(hybufocon A) = >93% (filofocon A) = >93% (pemufocon A) = >93%	>93%
g.	Refractive Index	(hybufocon A) = 1.44 (filofocon A) = 1.45 (pemufocon A) = 1.45	1.47

* captive bubble method

** receding angle method

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2 2003

Metro Optics, Inc.
c/o Ms. Deanna Werber
MedVice Consulting, Inc.
623 Glacier Drive
Grand Junction, CO 81503

Re: K024164
ComfortKone™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A)
Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank)
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid Gas Permeable Contact Lens
Regulatory Class: Class II
Product Code: HQD
Dated: December 9, 2002
Received: December 17, 2002

Dear Ms. Werber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: ComfortKone™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank)

INDICATIONS FOR USE:

The ComfortKone™ Keratoconus Aspheric (hybufocon A, filofocon A, pemufocon A) Rigid Gas Permeable (RGP) Daily Wear Contact Lens (Clear and Tinted, Lathe-cut from Lens Blank) is indicated for daily wear for persons requiring Keratoconus management with otherwise non-diseased eyes. The lens may be prescribed for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and not-aphakic persons. The lens may be disinfected with a chemical disinfection system.

(PLEASE DO OT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K024164